AMENDED IN SENATE MAY 20, 2010

AMENDED IN SENATE APRIL 27, 2010

AMENDED IN SENATE APRIL 12, 2010

SENATE BILL No. 1064

Introduced by Senator Alquist

February 16, 2010

An act to amend Sections 125290.20, 125290.30, 125290.40, 125290.45, and 125290.60 of, and to add Sections ~~125290.80, 125291.21, and 125291.90~~ *125290.71 and 125290.80* to, the Health and Safety Code, relating to stem cells.

LEGISLATIVE COUNSEL'S DIGEST

SB 1064, as amended, Alquist. California Stem Cell Research and Cures Act.

The California Stem Cell Research and Cures Act, an initiative measure approved by the voters at the November 2, 2004, statewide general election as Proposition 71, establishes the California Institute for Regenerative Medicine (CIRM), the purpose of which is, among other things, to make grants and loans for stem cell research, for research facilities, and for other vital research opportunities to realize therapies, protocols, and medical procedures that will result in the cure for, or substantial mitigation of, diseases and injuries. Existing law establishes the Independent Citizen's Oversight Committee (ICOC) composed of appointed members, that is required to perform various functions and duties with regard to the operation of the institute, including, but not limited to, establishing standards applicable to research funded by the institute. Existing law prohibits amendment of Proposition 71 by the Legislature unless the amendment is approved by the voters, or the

amendment is accomplished by a bill introduced after the first 2 full calendar years and approved by a vote of 70% of both houses, and only if the amendment enhances the ability of the institute to further the purposes of the grant and loan programs.

Existing law specifies the appointment process for the members of the ICOC, including the chairperson and vice chairperson who are employees of the ICOC, and provides that the chairperson and vice chairperson serve 6-year terms. Existing law defines the duties of the chairperson and the president of the ICOC and limits the total number of authorized employees of the CIRM to 50.

This bill would ~~reduce the terms of the chairperson and vice chairperson to 4-year terms, would require their terms to be staggered, and would~~ require the CIRM, under the guidance of the ICOC, to create a succession plan addressing changes in leadership in the CIRM and ICOC, as specified. The bill would ~~make prescribed changes to the duties of the chairperson and president of the ICOC and would~~ eliminate the 50-employee maximum for the CIRM.

The bill would also require the CIRM, under the guidance of the ICOC, to create, by January 31, 2012, a transition plan to address the expiration of current bond funding and to submit that plan to the Governor, the Controller, and the Legislature.

Existing law requires the CIRM to commission an independent financial audit, which is provided to the Controller for review and reported in the annual public report. Existing law establishes the Citizen's Financial Accountability Oversight Committee, chaired by the Controller, to review the annual audit and financial practices of the CIRM.

This bill would, *additionally,* require~~, every 6 years, commencing with the audit of the 2010–11 fiscal year, that the financial audit also include~~ a performance ~~component~~ *audit to be conducted every 3 years, as specified*. ~~The bill would also require, every 6 years, commencing with the audit of the 2013–14 fiscal year, the commissioning of a performance audit of the ICOC, as specified.~~

Existing law contains provisions relating to the extent to which requirements relating to the disclosure of public records applied to records of the CIRM.

This bill would require the ICOC to disclose, in all meeting minutes, a summary of vote tallies, including each board member's votes and recusals~~, and would require the ICOC to amend all past minutes to include this summary~~.

The act provides that the ICOC shall establish standards that require that all grants and loan awards under the act shall be subject to intellectual property agreements that balance the opportunity of the state to benefit from the patents, royalties, and licenses that result from basic research, therapy development, and clinical trials with the need to ensure that essential medical research is not unreasonably hindered by the intellectual property agreements.

This bill would require that intellectual property standards that the ICOC develops include a requirement that each grantee and the licensees of the grantee submit to the CIRM ~~for approval, 180 days before a drug is placed into commerce,~~ a plan that will afford ~~uninsured~~ Californians access to any drug that is, in whole or in part, the result of research funded by the CIRM, ~~and that the plan require that the grantees and licensees provide drugs to state and local government funded programs at one of the 3 benchmark prices in the California Discount Prescription Drug Program, provided for pursuant to existing law,~~ except when the ICOC adopts a waiver, as specified. The bill would also require ~~all revenues received from the intellectual property agreements to be deposited in the General Fund~~ *specified grant recipients to share a fraction of the revenue they receive from licensing or self-commercialization of an invention or technology that arises from research funded by CIRM, as specified*.

Existing law establishes the procedure by which grant and loan applications are processed and scored by the 15 scientist members of the Scientific and Medical Research Funding Working Group.

This bill would remove the 15 member limit, and *would instead require that a peer review panel consist of both scientists and patient advocates and require that there be 15 scientists on a peer review panel. The bill* would require all grant applications received by the ICOC to be sent to the Scientific and Medical Research Funding Working Group prior to any other process, unless the process is only to determine completeness of the application and to ensure that the application meets the grant program criteria.

~~Existing law establishes the California Stem Cell Research and Cures Fund in the State Treasury, into which the proceeds of the interim debt and bonds are deposited. The fund is continuously appropriated for the purposes specified in the act, including a limitation of 3% on the amount of bond funding that may be used for administrative costs.~~

~~This bill would define administrative costs for this purpose.~~

Vote: 70%. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares the following:

(a) The California Institute for Regenerative Medicine was established in 2004, through the passage of Proposition 71, for the purposes of implementing and managing a $3 billion investment in stem cell research on behalf of the state.

(b) Stem cell research is a promising area of research aimed at finding breakthrough cures for currently incurable diseases and injuries affecting millions of people. This investment, as stated in the proposition, would protect and benefit the California budget by funding scientific and medical research that will significantly reduce state health care costs in the future.

(c) Furthermore, the Legislative Analyst, in its official ballot information, stated that the state would "receive payments from patents, royalties, and licenses resulting from the research funded by the institute" through institute-established standards "requiring that all grants and loans be subject to agreements allowing the state to financially benefit from patents, royalties, and licenses resulting from the research activities funded under the measure."

(d) Since its inception, ~~many concerns and criticisms~~ *questions and concerns* have been raised about the institute's practices, its governing board, and how the state directly and financially benefits through this sizeable investment. These criticisms divert the attention and focus of the institute to drive transformational scientific research and find cures.

(e) It is the intent of ~~this act~~ *the Legislature* to further enhance the ability of the institute to manage this investment made with public funds by addressing public concerns regarding oversight and transparency.

(f) It is further the intent of this act to ensure that California maximizes its receipt of revenues generated through grants or loans made through the institute and with state funds.

(g) It is in the best interests of the state that therapies that are created in whole or in part by funding from the institute be made available to Californians who have no other means of purchasing

those therapies for reasons that include, but are not limited to, low income or the lack of available health insurance coverage.

(h) It is in the best interests of the state that the leadership of the institute, including the ICOC and the officers of the institute possess the qualities necessary to serve the needs of the institute, and that the chairperson of the ICOC and the president of the institute have well defined and complementary duties.

SEC. 2. Section 125290.20 of the Health and Safety Code is amended to read:

125290.20. ICOC Membership; Appointments; Terms of Office

(a) ICOC Membership

The ICOC shall have 29 members, appointed as follows:

(1) The Chancellors of the University of California at San Francisco, Davis, San Diego, Los Angeles, and Irvine shall each appoint an executive officer from his or her campus.

(2) The Governor, the Lieutenant Governor, the Treasurer, and the Controller shall each appoint an executive officer from the following three categories:

(A) A California university, excluding the five campuses of the University of California described in paragraph (1), that has demonstrated success and leadership in stem cell research, and that has:

(i) A nationally ranked research hospital and medical school; this criteria will apply to only two of the four appointments.

(ii) A recent proven history of administering scientific and/or medical research grants and contracts in an average annual range exceeding one hundred million dollars ($100,000,000).

(iii) A ranking, within the past five years, in the top 10 United States universities with the highest number of life science patents or that has research or clinical faculty who are members of the National Academy of Sciences.

(B) A California nonprofit academic and research institution that is not a part of the University of California, that has demonstrated success and leadership in stem cell research, and that has:

(i) A nationally ranked research hospital or that has research or clinical faculty who are members of the National Academy of Sciences.

(ii) A proven history in the last five years of managing a research budget in the life sciences exceeding twenty million dollars ($20,000,000).

(C) A California life science commercial entity that is not actively engaged in researching or developing therapies with pluripotent or progenitor stem cells, that has a background in implementing successful experimental medical therapies, and that has not been awarded, or applied for, funding by the institute at the time of appointment. A board member of that entity with a successful history of developing innovative medical therapies may be appointed in lieu of an executive officer.

(D) Only one member shall be appointed from a single university, institution, or entity. The executive officer of a California university, a nonprofit research institution or life science commercial entity who is appointed as a member, may from time to time delegate those duties to an executive officer of the entity or to the dean of the medical school, if applicable.

(3) The Governor, the Lieutenant Governor, the Treasurer, and the Controller shall appoint members from among California representatives of California regional, state, or national disease advocacy groups, as follows:

(A) The Governor shall appoint two members, one from each of the following disease advocacy groups: spinal cord injury and Alzheimer's disease.

(B) The Lieutenant Governor shall appoint two members, one from each of the following disease advocacy groups: type II diabetes and multiple sclerosis or amyotrophic lateral sclerosis.

(C) The Treasurer shall appoint two members, one from each of the following disease groups: type I diabetes and heart disease.

(D) The Controller shall appoint two members, one from each of the following disease groups: cancer and Parkinson's disease.

(4) The Speaker of the Assembly shall appoint a member from among California representatives of a California regional, state, or national mental health disease advocacy group.

(5) The President pro Tempore of the Senate shall appoint a member from among California representatives of a California regional, state, or national HIV/AIDS disease advocacy group.

~~(6) A chairperson and vice chairperson who shall be chosen from and elected by the ICOC members. The chairperson and vice chairperson shall each be elected for a term of four years, the terms~~

~~to be staggered. The chairperson and vice chairperson of ICOC shall be full- or part-time employees of the institute and shall meet the following criteria:~~

(6) A chairperson and vice chairperson who shall be elected by the ICOC members. Each constitutional officer shall nominate a candidate for chairperson and another candidate for vice chairperson. The chairperson and vice chairperson shall each be elected for a term of six years. The chairperson and vice chairperson of ICOC shall be full- or part-time employees of the institute and shall meet the following criteria:

(A) Mandatory Chairperson Criteria

(i) Documented history in successful stem cell research advocacy.

(ii) Experience with state and federal legislative processes that must include some experience with medical legislative approvals of standards and/or funding.

(iii) Qualified for appointment pursuant to paragraph (3), (4), or (5) of subdivision (a).

(iv) Cannot be concurrently employed by or on leave from any prospective grant or loan recipient institutions in California.

(B) Additional Criteria for Consideration:

(i) Experience with governmental agencies or institutions (either executive or board position).

(ii) Experience with the process of establishing government standards and procedures.

(iii) Legal experience with the legal review of proper governmental authority for the exercise of government agency or government institutional powers.

(iv) Direct knowledge and experience in bond financing.

The vice chairperson shall satisfy clauses (i), (iii), and (iv) of subparagraph (A). The vice chairperson shall be selected from among individuals who have attributes and experience complementary to those of the chairperson, preferably covering the criteria not represented by the chairperson’s credentials and experience.

(b) Appointment of ICOC Members

(1) All appointments shall be made within 40 days of the effective date of this act. In the event that any of the appointments are not completed within the permitted timeframe, the ICOC shall

proceed to operate with the appointments that are in place, provided that at least 60 percent of the appointments have been made.

(2) Forty-five days after the effective date of the measure adding this chapter, the Controller and the Treasurer, or if only one is available within 45 days, the other shall convene a meeting of the appointed members of the ICOC to elect a chairperson and vice chairperson from among the individuals nominated by the constitutional officers pursuant to paragraph (6) of subdivision (a).

(c) ICOC Member Terms of Office

(1) The members appointed pursuant to paragraphs (1), (3), (4), and (5) of subdivision (a) shall serve eight-year terms, and all other members shall serve six-year terms. Members shall serve a maximum of two terms.

(2) If a vacancy occurs within a term, the appointing authority shall appoint a replacement member within 30 days to serve the remainder of the term.

(3) When a term expires, the appointing authority shall appoint a member within 30 days. ICOC members shall continue to serve until their replacements are appointed.

SEC. 3. Section 125290.30 of the Health and Safety Code is amended to read:

125290.30. Public and Financial Accountability Standards

(a) Annual Public Report

The institute shall issue an annual report to the public which sets forth its activities, grants awarded, grants in progress, research accomplishments, and future program directions. Each annual report shall include, but not be limited to, the following: the number and dollar amounts of research and facilities grants; the grantees for the prior year; the institute's administrative expenses; an assessment of the availability of funding for stem cell research from sources other than the institute; a summary of research findings, including promising new research areas; an assessment of the relationship between the institute's grants and the overall strategy of its research program; and a report of the institute's strategic research and financial plans.

(b) ~~(1)~~ Independent Financial and Performance Audit for Review by Controller

~~The~~

(1) The institute shall annually commission an independent financial audit of its activities from a certified public accounting firm, which shall be provided to the Controller, who shall review the audit and annually issue a public report of that review. ~~Every six years, commencing with the audit of the 2010–11 fiscal year, the audit required pursuant to this subdivision shall include a performance component, which shall examine the programs, functions, operations, management systems, and policies and procedures of the institute to assess whether that entity is achieving economy, efficiency, and effectiveness in the employment of available resources.~~

~~(2) The performance component of the audit shall be conducted in accordance with government auditing standards, and shall include a review of whether the institute is complying with ICOC policies and procedures. The performance component of the audit shall give deference to the scientific judgment of the Scientific and Medical Research Funding Working Group. The first performance audit shall include, but not be limited to, all of the following:~~

~~(A) The strategic policies and plans developed by the institute.~~

(2) A performance audit shall be commissioned by the institute every three years beginning with the audit for the 2010–11 fiscal year. The performance audit, which may be performed by the Bureau of State Audits, shall examine the functions, operations, management systems, and policies and procedures of the institute to assess whether the institute is achieving economy, efficiency, and effectiveness in the employment of available resources. The performance audit shall be conducted in accordance with government auditing standards, and shall include a review of whether the institute is complying with ICOC policies and procedures. The first performance audit shall include, but not be limited to, all of the following:

~~(B)~~

(A) Policies and procedures for the issuance of contracts and grants and a review of a representative sample of contracts, grants, and loans executed by the institute.

~~(C)~~

(B) Policies and procedures relating to the protection or treatment of intellectual property rights associated with research funded or commissioned by the institute.

~~(3) In addition to the audit required in paragraph (1), the Citizen's Financial Accountability Oversight Committee shall, every six years, commencing with the audit of the 2013–14 fiscal year, commission and define the scope of a performance audit of the ICOC's activities from a certified public accounting firm. This audit shall also be included in the annually issued public report for that year. The performance audit shall be conducted in accordance with government auditing standards and include a review of the policies and procedures established by the ICOC to determine whether the ICOC has established a suitable structure for administering the institute, whether those policies and procedures comply with relevant laws, regulations, and best practices, and, to the extent possible, whether the institute is complying with those policies and procedures. The audit shall give deference to the scientific judgment of the Scientific and Medical Research Funding Working Group. The first audit shall include, but not be limited to, both of the following:~~

~~(A) The strategic policies and plans developed by the ICOC.~~

~~(B) Policies and procedures for the issuance of contracts, grants, and loans and a review of a representative sample of contracts, grants, and loans executed by the ICOC.~~

~~(4)~~

(3) All reasonable administrative costs of the audits required by ~~paragraphs (1) and (3)~~ *this subdivision* shall be paid by the institute.

(c) Citizen's Financial Accountability Oversight Committee

There shall be a Citizen's Financial Accountability Oversight Committee chaired by the Controller. This committee shall review the annual financial audit, the Controller's report and evaluation of that audit, and the financial practices of the institute. The Controller, the Treasurer, the President pro Tempore of the Senate, the Speaker of the Assembly, and the Chairperson of the ICOC shall each appoint a public member of the committee. Committee members shall have medical backgrounds and knowledge of relevant financial matters. The committee shall provide recommendations on the institute's financial practices and performance. The Controller shall provide staff support. The committee shall hold a public meeting, with appropriate notice, and with a formal public comment period. The committee shall evaluate public comments and include appropriate summaries in

its annual report. The ICOC shall provide funds for all costs associated with commissioning the performance audit, the per diem expenses of the committee members, and for publication of the annual report.

(d) Public Meeting Laws

(1) The ICOC shall hold at least two public meetings per year, one of which will be designated as the institute's annual meeting. The ICOC may hold additional meetings as it determines are necessary or appropriate.

(2) The Bagley-Keene Open Meeting Act, Article 9 (commencing with Section 11120) of Chapter 1 of Part 1 of Division 3 of Title 2 of the Government Code, shall apply to all meetings of the ICOC, except as otherwise provided in this section. The ICOC shall award all grants, loans, and contracts in public meetings and shall adopt all governance, scientific, medical, and regulatory standards in public meetings.

(3) The ICOC may conduct closed sessions as permitted by the Bagley-Keene Open Meeting Act, under Section 11126 of the Government Code. In addition, the ICOC may conduct closed sessions when it meets to consider or discuss:

(A) Matters involving information relating to patients or medical subjects, the disclosure of which would constitute an unwarranted invasion of personal privacy.

(B) Matters involving confidential intellectual property or work product, whether patentable or not, including, but not limited to, any formula, plan, pattern, process, tool, mechanism, compound, procedure, production data, or compilation of information, which is not patented, which is known only to certain individuals who are using it to fabricate, produce, or compound an article of trade or a service having commercial value and which gives its user an opportunity to obtain a business advantage over competitors who do not know it or use it.

(C) Matters involving prepublication, confidential scientific research or data.

(D) Matters concerning the appointment, employment, performance, compensation, or dismissal of institute officers and employees. Action on compensation of the institute's officers and employees shall only be taken in open session.

(4) The meeting required by paragraph (2) of subdivision (b) of Section 125290.20 shall be deemed to be a special meeting for the purposes of Section 11125.4 of the Government Code.

(e) Public Records

(1) The California Public Records Act, Article 1 (commencing with Section 6250) of Chapter 3.5 of Division 7 of Title 1 of the Government Code, shall apply to all records of the institute, except as otherwise provided in this section.

(2) Nothing in this section shall be construed to require disclosure of any records that are any of the following:

(A) Personnel, medical, or similar files, the disclosure of which would constitute an unwarranted invasion of personal privacy.

(B) Records containing or reflecting confidential intellectual property or work product, whether patentable or not, including, but not limited to, any formula, plan, pattern, process, tool, mechanism, compound, procedure, production data, or compilation of information, which is not patented, which is known only to certain individuals who are using it to fabricate, produce, or compound an article of trade or a service having commercial value and which gives its user an opportunity to obtain a business advantage over competitors who do not know it or use it.

(C) Prepublication scientific working papers or research data.

(3) The institute shall include, in all meeting minutes, a summary of vote tallies and disclosure of each board member's votes and ~~recusals. The institute shall amend past minutes to include a summary of vote tallies and disclosure of each board member's votes and recusals.~~ *recusals on all action items.*

(f) Competitive Bidding

(1) The institute shall, except as otherwise provided in this section, be governed by the competitive bidding requirements applicable to the University of California, as set forth in Article 1 (commencing with Section 10500) of Chapter 2.1 of Part 2 of Division 2 of the Public Contract Code.

(2) For all institute contracts, the ICOC shall follow the procedures required of the Regents by Article 1 (commencing with Section 10500) of Chapter 2.1 of Part 2 of Division 2 of the Public Contract Code with respect to contracts let by the University of California.

(3) The requirements of this section shall not be applicable to grants or loans approved by the ICOC.

(4) Except as provided in this section, the Public Contract Code shall not apply to contracts let by the institute.

(g) Conflicts of Interest

(1) The Political Reform Act, Title 9 (commencing with Section 81000) of the Government Code, shall apply to the institute and to the ICOC, except as provided in this section and in subdivision (e) of Section 125290.50.

(A) No member of the ICOC shall make, participate in making, or in any way attempt to use his or her official position to influence a decision to approve or award a grant, loan, or contract to his or her employer, but a member may participate in a decision to approve or award a grant, loan, or contract to a nonprofit entity in the same field as his or her employer.

(B) A member of the ICOC may participate in a decision to approve or award a grant, loan, or contract to an entity for the purpose of research involving a disease from which a member or his or her immediate family suffers or in which the member has an interest as a representative of a disease advocacy organization.

(C) The adoption of standards is not a decision subject to this section.

(2) Service as a member of the ICOC by a member of the faculty or administration of any system of the University of California shall not, by itself, be deemed to be inconsistent, incompatible, in conflict with, or inimical to the duties of the ICOC member as a member of the faculty or administration of any system of the University of California and shall not result in the automatic vacation of either such office. Service as a member of the ICOC by a representative or employee of a disease advocacy organization, a nonprofit academic and research institution, or a life science commercial entity shall not be deemed to be inconsistent, incompatible, in conflict with, or inimical to the duties of the ICOC member as a representative or employee of that organization, institution, or entity.

(3) Section 1090 of the Government Code shall not apply to any grant, loan, or contract made by the ICOC except where both of the following conditions are met:

(A) The grant, loan, or contract directly relates to services to be provided by any member of the ICOC or the entity the member represents or financially benefits the member or the entity he or she represents.

(B) The member fails to recuse himself or herself from making, participating in making, or in any way attempting to use his or her official position to influence a decision on the grant loan or contract.

(h) Patent Royalties and License Revenues Paid to the State of California

~~The~~

(1) The ICOC shall establish standards that require that all grants and loan awards be subject to intellectual property agreements that balance the opportunity of the State of California to benefit from the patents, royalties, and licenses that result from basic research, therapy development, and clinical trials with the need to ensure that essential medical research is not unreasonably hindered by the intellectual property agreements. All revenues received through the intellectual property agreements established pursuant to this subdivision shall be deposited into the General Fund.

(2) These standards shall include, at a minimum, a requirement that CIRM grantees, other than loan recipients and facilities grant recipients, share a fraction of the revenue they receive from licensing or self-commercializing an invention or technology that arises from research funded by CIRM, as set forth below. All revenues received pursuant to this paragraph or regulations adopted to implement this paragraph shall be deposited in the General Fund for use consistent with Section 202(c)(7) of Title 35 of the United States Code, if applicable.

(A) (i) A grantee that licenses an invention or technology that arises from research funded by CIRM shall pay 25 percent of the revenues it receives in excess of five hundred thousand dollars ($500,000), in the aggregate, to the General Fund. The threshold amount of five hundred thousand dollars ($500,000) shall be adjusted annually by a multiple of a fraction, the denominator of which is the Consumer Price Index, All Urban Consumers, All Items (San Francisco-Oakland-San Jose; 1982-84=100) as prepared by the Bureau of Labor Statistics of the United States Department of Labor and published for the month of October 2009, and the numerator of which is that index published for the month in which the grantee accepts the grant.

(ii) If funding sources other than CIRM directly contributed to the development of the invention or technology, then the return to the General Fund shall be calculated as follows: The amount of

CIRM funding for the invention or technology shall be divided by the total of funding provided by all sources, and that fraction shall be multiplied by 25. That numeral is the percentage due to the General Fund.

(B) (i) A grantee that self-commercializes a product that results from an invention or technology that arises from research funded by CIRM shall pay an amount to the General Fund equal to three times the total amount of the CIRM grant or grants received by the grantee in support of the research that contributed to the creation of the product. The rate of payback of the royalty shall be at a rate of 3 percent of the annual net revenue received by the grantee from the product.

(ii) In addition to the payment required by clause (i), the first time that net commercial revenues earned by the grantee from the product exceed two hundred fifty million dollars ($250,000,000) in a calendar year, the grantee shall make a one-time payment to the General Fund equal to three times the total amount of the grant or grants awarded by CIRM to the grantee in support of the research that contributed to the creation of the product.

(iii) In addition to the payments required by clauses (i) and (ii), the first time that net commercial revenues earned by the grantee from the product exceed five hundred million dollars ($500,000,000) in a calendar year, the grantee shall make an additional one-time payment to the General Fund equal to three times the total amount of the grant or grants awarded by CIRM to the grantee in support of the research that contributed to the creation of the product.

(iv) In addition to the payments required by clauses (i), (ii), and (iii), the first time that net commercial revenues earned by the grantee from the product equal or exceed five hundred million dollars ($500,000,000) in a calendar year, the grantee shall pay the General Fund 1 percent annually of net commercial revenue in excess of five hundred million dollars ($500,000,000) for the life of any patent covering the invention or technology, if the grantee patented its invention or technology and received a CIRM grant or grants amounting to more than five million dollars ($5,000,000) in support of the research that contributed to the creation of the product.

(3) The ICOC shall have the authority to adopt regulations to implement this subdivision. The ICOC shall also have the authority

to modify the formulas specified in subparagraphs (A) and (B) of paragraph (2) through regulations if the ICOC determines pursuant to paragraph (1) that a modification is required either in order to ensure that essential medical research, including, but not limited to, therapy development and the broad delivery of therapies to patients, is not unreasonably hindered, or to ensure that the State of California has an opportunity to benefit from the patents, royalties, and licenses that result from basic research, therapy development, and clinical trials. The ICOC shall notify the appropriate fiscal and policy committees of the Legislature 10 calendar days before exercising its authority to vote on the modification of the formulas specified in subparagraphs (A) and (B) of paragraph (2).

(i) Preference for California Suppliers

The ICOC shall establish standards to ensure that grantees purchase goods and services from California suppliers to the extent reasonably possible, in a good faith effort to achieve a goal of more than 50 percent of such purchases from California suppliers.

SEC. 4. Section 125290.40 of the Health and Safety Code is amended to read:

125290.40. ICOC Functions

The ICOC shall perform the following functions:

(a) Oversee the operations of the institute.

(b) Develop annual and long-term strategic research and financial plans for the institute.

(c) Make final decisions on research standards and grant awards in California.

(d) Ensure the completion of an annual financial audit of the institute's operations.

(e) Issue public reports on the activities of the institute.

(f) Establish policies regarding intellectual property rights arising from research funded by the institute.

(g) Establish rules and guidelines for the operation of the ICOC and its working groups.

(h) Perform all other acts necessary or appropriate in the exercise of its power, authority, and jurisdiction over the institute.

(i) Select members of the working groups.

(j) Adopt, amend, and rescind rules and regulations to carry out the purposes and provisions of this chapter, and to govern the procedures of the ICOC. Except as provided in subdivision (k),

these rules and regulations shall be adopted in accordance with the Administrative Procedure Act (Government Code, Title 2, Division 3, Part 1, Chapter 4.5, Sections 11371 et seq.).

(k) Notwithstanding the Administrative Procedure Act (APA), and in order to facilitate the immediate commencement of research covered by this chapter, the ICOC may adopt interim regulations without compliance with the procedures set forth in the APA. The interim regulations shall remain in effect for 270 days unless earlier superseded by regulations adopted pursuant to the APA.

(*l*) Request the issuance of bonds from the California Stem Cell Research and Cures Finance Committee and loans from the Pooled Money Investment Board.

(m) May annually modify its funding and finance programs to optimize the institute's ability to achieve the objective that its activities be revenue-positive for the State of California during its first five years of operation without jeopardizing the progress of its core medical and scientific research program.

(n) Notwithstanding Section 11005 of the Government Code, accept additional revenue and real and personal property, including, but not limited to, gifts, royalties, interest, and appropriations that may be used to supplement annual research grant funding and the operations of the institute.

(o) Under the guidance of the ICOC, the institute shall create a succession plan addressing changes in leadership of both the institute and the ICOC designed to minimize disruption and adverse impacts to the activities of the institute. A copy of the succession plan shall be transmitted to the Governor, Controller, and the Legislature within 30 days of its completion. The succession plan should include, but is not limited to:

~~(1) A statement of commitment to prepare for inevitable leadership change.~~

~~(2) A statement of commitment to assess~~

(1) An assessment of leadership needs before beginning a search.

~~(3) An outline of succession procedures, including, but not limited to, timeframe for making the interim appointment, timeframe for appointing a board transition committee, and the roles of the transition committee that would include, for example communication with stakeholders, identifying a transition management consultant, conducting an organizational assessment, and designing the search plan.~~

~~(4)~~

(2) An outline of succession procedures.

(3) Strategies to ensure successful knowledge transfer.

SEC. 5. Section 125290.45 of the Health and Safety Code is amended to read:

125290.45. ICOC Operations

(a) Legal Actions and Liability

(1) The institute may sue and be sued.

(2) Based upon ICOC standards, institute grantees shall indemnify or insure and hold the institute harmless against any and all losses, claims, damages, expenses, or liabilities, including attorneys' fees, arising from research conducted by the grantee pursuant to the grant, and/or, in the alternative, grantees shall name the institute as an additional insured and submit proof of such insurance.

(3) Given the scientific, medical, and technical nature of the issues facing the ICOC, and notwithstanding Section 11042 of the Government Code, the institute is authorized to retain outside counsel when the ICOC determines that the institute requires specialized services not provided by the Attorney General's office.

(4) The institute may enter into any contracts or obligations which are authorized or permitted by law.

(b) Personnel

(1) The ICOC shall from time to time determine the total number of authorized employees for the institute, excluding members of the working groups who shall not be considered institute employees. The ICOC shall select a chairperson, vice chairperson, and president who shall exercise all of the powers delegated to them by the ICOC. The following functions apply to the chairperson, vice chairperson, and president:

~~(A) The chairperson's role is to provide leadership to the ICOC and does not include tasks associated with the day-to-day management of the institute. The chairperson's responsibilities shall be determined by the majority of the board and may include providing oversight of the ICOC agenda and workflow including all evaluations and approvals of scientific and medical working group grants, loans, facilities, and standards evaluations, managing and optimizing the institute's bond financing plans and funding cashflow plan; interfacing with the California Legislature, the United States Congress, the California health care system, and the~~

~~California public; and optimizing all financial leverage opportunities for the institute. The chairperson may also serve as a member of the Scientific and Medical Accountability Standards Working Group and the Scientific and Medical Research Facilities Working Group and as an ex officio member of the Scientific and Medical Research Funding Working Group. The vice chairperson's primary responsibilities are to support the chairperson in all duties and to carry out those duties in the chairperson's absence.~~

~~(B) The president's role is to manage the day-to-day operations and to serve as the chief executive of the institute. The president's tasks may include, but are not limited to, recruiting the highest scientific and medical talent in the United States to serve the institute on its working groups; serving the institute on its working groups; directing ICOC staff and participating in the process of supporting all working group requirements to develop recommendations on grants, loans, facilities, and standards as well as directing and supporting the ICOC process of evaluating and acting on those recommendations, the implementation of all decisions on these and general matters of the ICOC; hiring, directing, and managing the staff of the institute; developing the budgets and cost control programs of the institute; managing compliance with all rules and regulations on the ICOC, including the performance of all grant recipients; leading negotiations for intellectual property agreements, policies, and contract terms; and managing and executing all intellectual property agreements and any other contracts pertaining to the institute or research it funds.~~

(A) The chairperson's primary responsibilities are to manage the ICOC agenda and workflow including all evaluations and approvals of scientific and medical working group grants, loans, facilities, and standards evaluations, and to supervise all annual reports and public accountability requirements; to manage and optimize the institute's bond financing plans and funding cashflow plan; to interface with the California Legislature, the United States Congress, the California health care system, and the California public; to optimize all financial leverage opportunities for the institute; and to lead negotiations for intellectual property agreements, policies, and contract terms. The chairperson shall also serve as a member of the Scientific and Medical Accountability Standards Working Group and the Scientific and Medical Research Facilities Working Group and as an ex officio member of the

Scientific and Medical Research Funding Working Group. The vice chairperson's primary responsibilities are to support the chairperson in all duties and to carry out those duties in the chairperson's absence.

(B) The president's primary responsibilities are to serve as the chief executive of the institute; to recruit the highest scientific and medical talent in the United States to serve the institute on its working groups; to serve the institute on its working groups; to direct ICOC staff and participate in the process of supporting all working group requirements to develop recommendations on grants, loans, facilities, and standards as well as to direct and support the ICOC process of evaluating and acting on those recommendations, the implementation of all decisions on these and general matters of the ICOC; to hire, direct, and manage the staff of the institute; to develop the budgets and cost control programs of the institute; to manage compliance with all rules and regulations of the ICOC, including the performance of all grant recipients; and to manage and execute all intellectual property agreements and any other contracts pertaining to the institute or research it funds.

(2) Each member of the ICOC except, the chairperson, vice chairperson, and president, shall receive a per diem of one hundred dollars ($100) per day (adjusted annually for cost of living) for each day actually spent in the discharge of the member's duties, plus reasonable and necessary travel and other expenses incurred in the performance of the member's duties.

(3) The ICOC shall establish daily consulting rates and expense reimbursement standards for the ~~non-ICOC~~ members of all of its working groups.

(4) Notwithstanding Section 19825 of the Government Code, the ICOC shall set compensation for the chairperson, vice chairperson, and president and other officers, and for the scientific, medical, technical, and administrative staff of the institute within the range of compensation levels for executive officers and scientific, medical, technical, and administrative staff of medical schools within the University of California system and the nonprofit academic and research institutions described in paragraph (2) of subdivision (a) of Section 125290.20.

SEC. 6. Section 125290.60 of the Health and Safety Code is amended to read:

125290.60. Scientific and Medical Research Funding Working Group

(a) Membership

The Scientific and Medical Research Funding Working Group shall have *at least* 23 members as follows:

(1) Seven ICOC members from the 10 disease advocacy group members described in paragraphs (3), (4), and (5) of subdivision (a) of Section 125290.20.

(2) ~~Fifteen~~ *At least 15* scientists nationally recognized in the field of stem cell research.

(3) The Chairperson of the ICOC.

(b) Functions

The Scientific and Medical Research Funding Working Group shall perform the following functions:

(1) Recommend to the ICOC interim and final criteria, standards, and requirements for considering funding applications and for awarding research grants and loans.

(2) Recommend to the ICOC standards for the scientific and medical oversight of awards.

(3) Recommend to the ICOC any modifications of the criteria, standards, and requirements described in paragraphs (1) and (2) above as needed.

(4) Review grant and loan applications based on the criteria, requirements, and standards adopted by the ICOC and make recommendations to the ICOC for the award of research, therapy development, and clinical trial grants and loans.

(5) Conduct peer group progress oversight reviews of grantees to ensure compliance with the terms of the award, and report to the ICOC any recommendations for subsequent action.

(6) Recommend to the ICOC standards for the evaluation of grantees to ensure that they comply with all applicable requirements. Such standards shall mandate periodic reporting by grantees and shall authorize the Scientific and Medical Research Funding Working Group to audit a grantee and forward any recommendations for action to the ICOC.

(7) Recommend its first grant awards within 60 days of the issuance of the interim standards.

(c) Recommendations for Awards

Award recommendations shall be based upon a competitive evaluation as follows:

~~(1) Only~~ *A peer review panel shall consist of both scientists and patient advocates. There shall be 15 scientists on a peer review panel. Only* the scientist members of the Scientific and Medical Research Funding Working Group shall score grant and loan award applications for scientific merit. Such scoring shall be based on scientific merit in three separate classifications—research, therapy development, and clinical trials, on criteria including the following:

~~(A)~~

(1) A demonstrated record of achievement in the areas of pluripotent stem cell and progenitor cell biology and medicine, unless the research is determined to be a vital research opportunity.

~~(B)~~

(2) The quality of the research proposal, the potential for achieving significant research, or clinical results, the timetable for realizing such significant results, the importance of the research objectives, and the innovativeness of the proposed research.

~~(C)~~

(3) In order to ensure that institute funding does not duplicate or supplant existing funding, a high priority shall be placed on funding pluripotent stem cell and progenitor cell research that cannot, or is unlikely to, receive timely or sufficient federal funding, unencumbered by limitations that would impede the research. In this regard, other research categories funded by the National Institutes of Health shall not be funded by the institute.

~~(D)~~

(4) Notwithstanding ~~subparagraph (C)~~ *paragraph (3)*, other scientific and medical research and technologies and/or any stem cell research proposal not actually funded by the institute under ~~subparagraph (C)~~ *paragraph (3)* may be funded by the institute if at least two-thirds of a quorum of the members of the Scientific and Medical Research Funding Working Group recommend to the ICOC that such a research proposal is a vital research opportunity.

~~(2) All grant applications received by the institute shall be sent, upon receipt, to the Scientific and Medical Research Funding Working Group for peer review prior to any other review process, unless the process is only to determine completeness of the application or to ensure that the application meets the grant program criteria. An individual reviewing an application prior to review by the Scientific Medical Research Funding Working Group shall, at minimum, meet the same conflict-of-interest rules that~~

~~apply to a non-ICOC member of the Scientific Medical Research Funding Working Group, as adopted by the ICOC pursuant to paragraph (1) of subdivision (e) of Section 125290.50.~~

~~SEC. 7. Section 125290.80 is added to the Health and Safety Code, to read:~~

~~125290.80. (a) The intellectual property standards that the ICOC develops shall include a requirement that each grantee and the licensee of the grantee submit a plan to the institute that will afford uninsured Californians access to any drug that is, in whole or in part, the result of research funded by the CIRM.~~

~~(b) The ICOC shall require submission of the plan required by subdivision (a) 180 days before a drug is placed into commerce. The plan shall be subject to the approval of the CIRM, after a public hearing and opportunity for public comment.~~

~~(c) (1) A plan created pursuant to subdivision (a) shall require each grantee and any licensee of the grantee that sells drugs that are, in whole or in part, the result of research funded by CIRM to provide those drugs to California state and local government funded programs at one of the three benchmark prices in the California Discount Prescription Drug Program (Division 112 (commencing with Section 130500)), as it exists on December 31, 2010.~~

~~(2) Paragraph (1) shall not preclude a public agency from obtaining prices that are lower than the price determined as described in paragraph (1) through negotiation, bulk purchasing, or another purchasing arrangement and shall not be construed to conflict with, or preempt, any other provision of state or federal law or regulation that would result in lower drug prices.~~

~~(d) For purposes of this section, "drug" includes an article recognized in the United States Pharmacopeia or the National Formulary, as those documents exist on December 31, 2010, an article intended for the diagnosis, cure, mitigation, or prevention of disease in humans or animals, or an article intended for use as a component thereof, and shall include therapeutic products, including, but not limited to, blood, blood products, cells, and cell therapies.~~

~~(e) The ICOC may waive the requirement in subdivision (c) only when both of the following conditions are met:~~

~~(1) Either of the following:~~

~~(A) The drug shall be used for the diagnosis, cure, mitigation, or prevention of a rare disease or condition, as recognized by the~~

~~federal Food and Drug Administration under Section 360bb of Title 21 of the United States Code, by individuals who would not otherwise have access to the drug through private insurance or public programs, the number of individuals who will have increased access to the drug represent a significant proportion of the individuals in California who have that rare disease or condition, and the ICOC has made a determination that, in the absence of the waiver, development of the drug will be impeded.~~

~~(B) The grantee commits, in writing, to provide expanded access to a drug under its access plan to a class of patients who would not otherwise receive access to the drug, including working uninsured individuals who do not qualify for any public program or private health plan or policy that provides coverage of the drug and the ICOC anticipates that the waiver will provide significant benefits that equal or exceed the benefits that would otherwise accrue to the state through the pricing requirements set forth in subdivision (c).~~

~~(2) The ICOC has conducted a public hearing prior to adopting the waiver.~~

~~(f) All revenues derived from patents, royalties, and licenses generated as a result of intellectual property agreements entered into pursuant to this subdivision shall be deposited into the General Fund.~~

~~SEC. 8. Section 125291.21 is added to the Health and Safety Code, to read:~~

~~125291.21. Administrative costs, as provided for in paragraph (2) of subdivision (a) of Section 125291.20, shall include all costs incurred in the operation and administration of the institute, the ICOC, and the Citizen's Financial Accountability Oversight Committee, costs resulting from contracts entered into for the purchase or lease of goods or services, including, but not limited to, the costs of supplies, materials, independent audit services, independent studies, reimbursement of costs provided to the CIRM, the ICOC, or the Citizen's Financial Accountability Oversight Committee provided by other governmental entities and required to be reimbursed, and for the costs of any other goods or services necessary to effectuate the purpose of the California Stem Cell Research and Cures Bond Act.~~

~~SEC. 9. Section 125291.90 is added to the Health and Safety Code, to read:~~

~~125291.90. Under the guidance of the ICOC, the institute shall, by January 31, 2012, create a transition plan addressing the expiration of current bond funding by January 1, 2014. A copy of the transition plan shall be transmitted to the Governor, the Controller, and the Legislature within 30 days of its completion.~~

SEC. 7. Section 125290.71 is added to the Health and Safety Code, to read:

125290.71. Under the guidance of the ICOC, the institute shall, by January 31, 2012, create a transition plan addressing the expiration of current bond funding. A copy of the transition plan shall be transmitted to the Governor, the Controller, and the Legislature within 30 days of its completion.

SEC. 8. Section 125290.80 is added to the Health and Safety Code, to read:

125290.80. The intellectual property standards that the ICOC develops shall include:

(a) A requirement that each grantee or the exclusive licensee of the grantee submit a plan to CIRM to afford access to any drug that is, in whole or in part, the result of research funded by CIRM to Californians who have no other means to purchase the drug. The access plan must be consistent with industry standards at the time of commercialization in California, accounting for the size of the market for the drug, and the resources of the grantee or exclusive licensee.

(b) A requirement that the grantee or exclusive licensee either submit the plan required by subdivision (a), seek an extension from CIRM, or notify CIRM of its intention to seek a waiver, within 10 business days following final approval of the drug by the federal Food and Drug Administration. If the grantee seeks an extension, the plan must be submitted within 30 business days following final approval of the drug by the federal Food and Drug Administration. The plan shall be subject to the approval of CIRM, after a public hearing and opportunity for public comment.

(c) A process by which the ICOC may waive the requirement in subdivision (a) if the ICOC determines, after a public hearing, that in the absence of the waiver, development and broad delivery of the drug will be unreasonably hindered or that the waiver will provide significant benefits that equal or exceed the benefits that would otherwise flow to the state pursuant to subdivision (a). The process shall include the requirement that a request for a waiver

shall be posted on CIRM's Internet Web site for a minimum of 10 business days in advance of the public hearing and that CIRM shall notify the Legislature if the ICOC grants a waiver request, including the reasons that justified the waiver request.

(d) Procedures to protect from public disclosure proprietary information submitted by grantees and exclusive licensees to CIRM pursuant to this section.

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